REMARKS

In the Office Action, Claims 27-31, 33, 34, 78-81, 97, 98, 107, and 108 were rejected over the prior art as discussed below. In this Amendment, Claims 27 and 80 have been amended, Claim 113 has been added, and no claims have been canceled. Thus, Claims 27-31, 33, 34, 78-81, 97, 98, 107, 108, and 113 remain pending for further consideration.

Personal Interview

Applicant thanks the Examiner for the courteous and helpful personal interview conducted on November 17, 2010 (summarized above).

Amendments to the Drawings

As discussed in the Interview, new Figure 3A is added to illustrate the positioning capability of an anchor zone of a catheter as claimed herein relative to the anatomy. Support for Figure 3A and the corresponding amendments to the specification can be found throughout the specification, for example in Figure 3 and paragraphs [0045], [0048]-[0049], and [0072]-[0073].

For example, Paragraph [0045] and Figure 3 describe the tortuous path referenced an orientation catheter 11 takes if delivered via the inferior vena cava 14 to the ascending aorta 9. This tortuous path proceeds from the inferior vena cava 14 into the right atrium 15, trans-septally into the left atrium 1, then between the anterior leaflet 3 and posterior leaflet 4 leaflet of the mitral valve into the ventricle in one technique. The catheter 11 and a catheter 18 (now shown in Figure 3A) are described as traversing this tight curve of the anatomy and thereafter proceeding into the left ventricular outflow tract 10 and, potentially, through the aortic valve 8 into the ascending aorta 9. The Specification states, for example, that "[i]n one embodiment, the orientation catheter once in place in the ascending aorta may be removed over a guide wire and the device Housing Catheter 18 advanced over the wire until its distal end is in the ascending aorta." ¶ [0049].

Rejections Under 35 U.S.C. § 103

Claims 27-31, 33, 34, 78-81, 97, 98, 107, and 108 were rejected in the Office Action under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,136,010 to Modesitt et al. (Modesitt)

in view of U.S. Patent No. 6,165,183 to Kuehn et al. (Kuehn) and U.S. Patent No. 6,752,813 to Goldfarb et al. (Goldfarb). Applicant disagrees with this rejection, but has made certain amendments consistent with the discussion at the interview to distinguish the prior art.

Modesitt

Modesitt is directed to a vessel closure device 10 for closing vessel wall punctures. Figures 1 and 11B show that the device 10 includes an articulatable foot near a distal end 16 of a shaft 12 that is inserted through a vessel penetration and actuated so that the foot extends along an axis of the vessel (i.e., a luminal axis). A monorail guidebody 22 extends distally of distal end 16 of shaft 12.

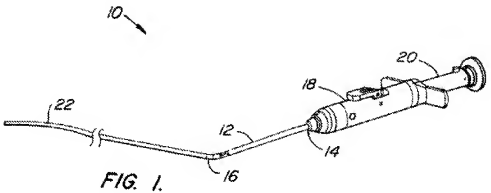
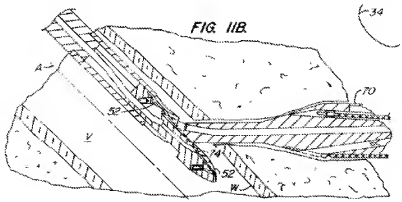


FIG. 1.

The guidebody 22 enables the device 10 to be advanced over a guidewire into the vessel through a vessel puncture and aligns a distal portion of the device 10 with the axis of vessel. As shown in Figure 11B, the device 10 in Modesitt is positioned in a substantially linear blood vessel and the guide body 22 is substantially straight when the vessel closure procedure is being carried out.



The guide body 22 apparently traverses a small angle bend, i.e., less than 50 degrees, when passing form a tissue tract into the blood vessel V. However, there is no basis to conclude that the device 10 could follow the tortuous vasculature from a peripheral vessel to a hear chamber. Applicant notes, for example, that instructions for a corresponding product of the same assignee of Modesitt say "[d]o not insert the SMC device into the fermoral artery at an angle greater than 45 degrees to the longitudinal plane of the artery." *Perclose A-T Suture Mediated Closure System* at p. 3 (submitted herewith in an Information Disclosure Statement).

The portion of the device 10 proximal to the articulatable foot 24 does not require or have flexibility required by the claim. In particular, Modesitt states that the shaft 12 "comprises an outer casing of a biocompatible material **such as stainless steel, carbon fiber, nylon, another suitable polymer, or the like** . . . . In some embodiments, shaft 12 may comprise a carbon fiber filled nylon, or carbon fiber filled with an alternative material." Modesitt at 8:45-53. Although mentioning "other polymers", it is clear from the manner of using the Modesitt device that the shaft 12 (i.e., the portion of the device 10 proximal of the foot 24) must be rigid and not flexible at least because the device is designed to be advanced directly downwardly through tissue to a peripheral blood vessel. See, e.g., Figures 13A-13C. If the shaft 12 were flexible the shaft would collapse and not be advanced within the tissue between the skin and the peripheral vessel.

While more flexible catheters can be advanced into blood vessels, such a result is generally achieved by first placing a guide catheter. The use of a guide catheter around the shaft 12 from the skin to the blood vessel wall apparently would interfere with advancement of the needles 38 through the tissue to the vessel wall. See, e.g., Figure 13D. Accordingly, while other prior art may show a catheter body that can be advanced to the heart, the combination of Modesitt with such a reference is contrary to the teachings of Modesitt.

Kuehn

The Office Action is not completely clear on what teachings of Kuehn are relied upon. The Office Action states, while discussing the teachings of Modesitt, that "the anchor zone is configured to orient and anchor the catheter so that the at least one tissue manipulator (440) can be positioned at the valve." Office Action at 3. In past office actions, the grasper 440 of Kuehn has been discussed by the Examiner, but precisely what modifications of Modesitt are provided by Kuehn is not clear.

Nevertheless, Kuehn has been discussed in prior responses, such as in the Response filed June 18, 2007. In the June, 2007 response, it was noted that Kuehn is directed to a device for heart valve repair in connection with Figures 20-21 that includes a gripper 438 with a plunger 446 that is used to direct leaflets of the valve to gripper arms or "graspers" 440. The graspers 440 are mounted on a grasper tube 441.

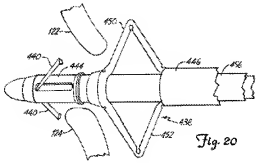


Fig. 20

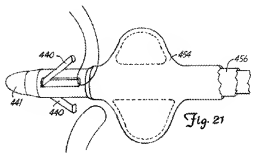


Fig. 21

The Examiner previously asserted that the grasper tube 441 is an "anchor zone," but as discussed in the Interview, there is no suggestion that the tip of the grasper tube 441 could be an anchor zone as claimed herein. Applicants disagree that Kuehn discloses any sort of anchor zone at the distal end of the grasper tube 441. In fact, Kuehn teaches away from locating any structure distal of the graspers 440 that would interact with tissue so as to provide any positioning or orienting capabilities. For example, although the distal end of the grasper tube 441 is not discussed in any detail in Kuehn, it is illustrated as being very short compared to the graspers 440. The graspers 440 are described as being "less than about 10 mm in length." Kuehn at 10:2-3. Thus, Kuehn teaches keeping the section of the gripper 438 distal of the graspers 440 very close to the area through which the valves move, and no longer. While the discussion of the distal end of the grasper tube 441 does not explain why confining the distal end to this space is important, one reason may be that a longer structure in Kuehn's device would create a substantial

risk of entanglement with the chordae tendinae that extend from the valve leaflets through the left ventricle.

Moreover, Kuehn teaches that any structure to position the graspers 440 relative to the valve leaflets should be located proximally of the graspers 440. In particular, the plungers 446, 454 are used to bring the leaflets into engagement with the graspers 440. Kuehn states that "as plunger 446 or 454 reaches a certain position relative to graspers 440 so that graspers 440 are within reach of leaflets 122, 124, shaft 456 is pulled back to retract graspers 440, which clasp leaflets 122, 124 between graspers 440 and grasper tube 441." Kuehn at 9:61-65. Thus, in both variations, Kuehn teaches locating proximally of the graspers 440 a structure that is for bringing the graspers 440 into a position in which the graspers 440 engage the leaflets. Kuehn expresses no reason to add another structure distal of the graspers 440 that would engage the heart or a vessel to provide an orienting or positioning function because the valve leaflets will be gripped between the proximal plungers 446, 454 and the graspers 440.

In addition, because Kuehn teaches towards using a proximally located mechanism for bringing the graspers 440 into engagement with the valve leaflets, a person of ordinary skill in the art looking to improve on the positioning feature would naturally consider alternative plunger-like features designed to directly engage the valve leaflets from a proximal location, i.e., within the atrium.

Therefore, Kuehn teaches away from an anchor zone, e.g., a distally placed structure that is useful for positioning or orienting the device. However, a modification of the device 10 of Modesitt to enable the device 10 to be placed at the heart valve would be contrary to Modesittt. Therefore, Applicant traverses this combination.

Goldfarb

Goldfarb is relied upon to show independent movable arms in Figure 14, reproduced below.

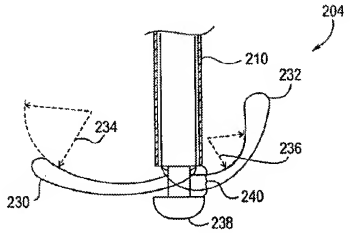


Fig. 14

However, Goldfarb is much like Kuehn in teaching that only a very short structure distal of the "distal elements" 230, 232 is appropriate. In particular, the only structure distal the element 230, 232 is a cap 238 which moves axially by a short distance to adjust the rigidity or curvature of the elements 230, 232 or to pinch the leaflets between the cap 238 and the shaft 210. See, e.g., Goldfarb 15:36-47. But, more significantly, Goldfarb teaches away from any sort of anchor zone distal of the element 230, 232. Goldfarb states

> The cap 238 may also be moveable to close a gap 240 between the cap 238 and the shaft 210 where the distal elements 230, 232 emerge. When the elements 230, 232 are retracted, movement of the cap 238 to close the gap ***minimizes the profile of the tool 204*** and ***reduces the possibility of the elements 230, 232 or portions of the device 204 interfering with tissue or entangling with chordae***.

Goldfarb at 15:28-36.

Therefore, Goldfarb and Kuehn are both contrary in their teachings to the claims herein and cannot form the basis for an obviousness rejection with other references.

Cribier

Cribier has been discussed at length in prior responses. See, e.g., *Response to Office Action* filed March 21, 2008, p 11. Applicant submits that a prima facie rejection cannot be based upon Cribier and the art cited herein at least because the combination would be improper and would fail to teach all of the limitations recited in the present claims.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, issuance of a Notice of Allowance is most earnestly solicited.

Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, Andrew M. Douglas at (949) 721-7623 to resolve such issue(s) promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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